Attachment G
Predicate Device Comparison Table

Device Name	Sponsor	510(k) Number	Indications for Use	FDA Comments
Restore® Orthobiologic Soft Tissue Implant	DePuy, Inc.	K982330	The DePuy OrthoTech Restore Orthobiologic Soft Tissue Implant is intended for use in **general surgical procedures** for reinforcement of soft tissue where weakness exists.	• Material – porcine Small Intestine Submucosa (SIS) (predominantly Collagen Type I & III) • Shape – Round, diameter 63.5mm, 10 plys (0.2mm thick)
		K001738	The DePuy Restore Orthobiologic Soft Tissue Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. In addition, the implant is intended for use in the specific application of **reinforcement of the soft tissues, which are repaired by suture or suture anchors limited to the supraspinatus during rotator cuff repair surgery.**	• Material – Identical to K982330 material • Design – same design as K982330 • Device not intended to be significant load bearing structures in shoulder since the sutures and suture anchors that reattach tissue to the bone may serve as the source of mechanical strength for the repair rather than the mesh itself serving as such source • Standard of care for the procedures indicate the patient undergoes a passive range of motion during most of the healing period and the limb will not experience heavy loads during this time

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Restore® Orthobiologic Soft Tissue Implant	DePuy, Inc.	K031969	The DePuy® Restore Orthobiologic Soft Tissue Implant is intended for use in general surgical procedures for reinforcement of soft tissue where weakness exists. In addition, the implant is intended for use in the **specific application of reinforcement of the soft tissues, which are repaired by suture or suture anchors, during rotator cuff repair surgery.** The Restore® Implant is not intended to replace normal body structure or provide the full mechanical strength to repair the rotator cuff. Sutures to repair the tear and suture or bone anchors to reattach the tissue to the bone provide mechanical strength for the rotator cuff repair. The Restore® Implant reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.	• Material – porcine Small Intestine Submucosa (SIS) (predominantly Collagen Type I & III) • Shape – Round, diameter 63.5mm, 10 plys (0.2mm thick) • Description – Not the frank repair for the rotator cuff tissue. Sutures and suture anchors that reattach tissue to the bone provide the necessary mechanical strength for the repair.
BioBlanket Surgical Mesh	Kensey Nash, Corp.	K041923	BioBlanket™ Surgical Mesh is indicated for use in general surgical procedures for **reinforcement of soft tissue where weakness exists and for the repair of ruptured or damaged soft tissues.** The device is intended for one time use.	• Material – Bovine Hide Collagen and Tween 80 • Maximum of 15% soluble collagen • Size – 5 cm (width) 5 or 10 cm (Length) and 1 mm thickness

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BioBlanket Surgical Mesh	Kensey Nash, Corp.	K043259	BioBlanket™ Surgical Mesh is indicated for use in general surgical procedures for the reinforcement and repair of soft tissue where weakness exists including, but **not limited to defects of the thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture line reinforcement and reconstructive procedures.** The device is also intended for **reinforcement of the soft tissues which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery.** The device is intended for one time use.	• Material – Bovine Hide Collagen and Tween 80 • Maximum of 20% soluble collagen • Design - variety of shapes (rectangles, squares, and circles) • Dimensions - 1 x 1 cm to 10 x 10 cm, and thicknesses 0.5 mm to 5 mm • Description – Used as a patch over the defect to provide additional reinforcement in the weak area of the soft tissue wall.
SIS Fistula Plug	Cook Biotech, Inc.	K050337	The SIS Fistula Plug is for implantation to **reinforce soft tissue where a rolled configuration is required, for repair of anal, rectal, and enterocutaneous fistulas**. The device is supplied sterile and is intended for one-time use.	• Material - Porcine small intestine • Identical to predicate Cook Biosciences SurgiSis meshes. • The material will now be formed into tubular or conical shapes. • The rolled device will be 2mm at the tapered end, 7mm at the proximal end, and 10 cm long. The Plug will be supplied in sheets ranging from 2x3cm to 7x10 cm, and 0.3mm thick. • The device acts as a seton.
OrthoMend / TissueMend	TEI Bio-sciences	K031188	OrthoMend is intended for surgical implantation to reinforce soft tissue where weakness exists and for the **repair of damaged or ruptured soft tissue membranes**. In addition, the device is intended to **reinforce soft tissues that are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff surgery.**	• Collagen matrix derived from the skin of fetal bovine • OrthoMend is identical to the predicate TissueMend • Thickness – 0.2–2mm • Sizes ranging from 8–350 cm^2 (i.e. 2x7, 4x7, 2x12, 4x12, and 8x12cm)

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OrthoMend / TissueMend	TEI Bio-sciences	K051766	OrthoMend Soft Tissue Repair Matrix is intended for reinforcement of soft tissues repaired by sutures or suture anchors, during tendon repair surgery, including **reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.** OrthoMend Soft Tissue Repair Matrix is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear and sutures or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair. OrthoMend Soft Tissue Repair Matrix reinforces soft tissue and provides a remodelable scaffold that is replaced by the patient's own soft tissues.	• Identical device to K031188 • Device is a thin sheet used to wrap around the component being repaired to reinforce during healing.
SIS Hernia Repair Device	Senmed Medical Ventures	K974540	The SIS Hernia Repair Device is intended to be implanted to **reinforce soft tissues where weakness exists**. Indications for use include the **repair of a hernia or body wall defect.** The device is intended for one-time use.	• Material: Porcine derived SIS • Dimensions: 5 x 8 cm to 20 cm to 30 cm, thickness: 0.5 – 1.0mm • Used as a covering to aid in the natural tissue healing of defects
SurgiSis	Cook Biotech, Inc.	K980431	Surgi*SIS*™ is intended for implantation to **reinforce soft tissue.** This device is intended for one-time use.	• Material: Porcine derived SIS • Lyophilized or hydrated sheets • Dimensions: 2 x 4 cm to 20 x 40 cm, thickness 40 µm to 700µm

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SurgiSis™ Sling	Cook Biotech, Inc	K992159	Surgi*SIS*™ is intended for implantation to **reinforce soft tissues where weakness exists in urological, gynecological, and gastroenterological anatomy including but not limited to the following procedures: pubourethal support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, and sacrocolposuspension**. By providing pubourethal support, the SurgiSis™ Sling may be used for the **treatment of urinary incontinence resulting from hypermobility or intrinsic sphincter deficiency**. The device is intended for on-time use.	• Material: Porcine SIS, identical to K980431 • Dimensions: 20 cm^2 to 140 cm^2 and having a nominal thickness of 70 µm to 600 µm

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SurgiSis® Staple Line Reinforce-ment	Cook Biotech, Inc	K022044	The SurgiSis® Staple Line Reinforcement is intended for use **as a prosthesis for the surgical repair of soft tissue deficiencies using surgical staplers**. The device may be used for **buttressing and reinforcing staple lines during lung resection (*e.g.,* wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy / pneumectomy, pneumoreduction) and other incisions and excisions of the lung and bronchus.** The device can be used for the **reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. The device can also be used for abdominal and thoracic wall repair, muscle flap reinforcement, rectal and vaginal prolapse repair, reconstruction of the pelvic floor, and repair of hernias *(e.g.,* diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical**). The SurgiSis® Staple Line Reinforcement may be used with anastomotic staplers or with non-anastomotic staplers. The device is intended for one-time use.	• Material: Identical to K980431, porcine SIS • Design: Differs in configuration from K980431, provided in a strip configuration intended for use in staple-line reinforcement during various surgical procedures using staplers. • Dimensions: 1 x 10.7 cm, 1.2 x 13.2 cm, and 1.2 x 17.3 cm with a nominal thickness of 350 µm
SIS Plastic Surgery Matrix	Cook Biotech, Inc.	K034039	The SIS Plastic Surgery Matrix Is for implantation to **reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery**. The device is supplied sterile and is intended for one-time use.	• Material: Porcine SIS • Proposed device is comprised of the same SIS material and undergoes the same manufacturing processes as the predicate device (i.e., Surgisis Soft Tissue Graft). • Device sold solely in a lyophilized state • Design: Single or multi-layer rectangular strand configurations. • Dimensions: 2–70 mm in width and up to 20 cm in length. Thicknesses will vary from 100– 1500 microns.

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SIS Facial Implant	Cook Biotech, Inc.	K050246	The SIS Facial Implant is intended for use to provide **soft tissue repair or reinforcement in plastic and reconstructive surgery of the face and head**. The device is supplied sterile and is intended for one-time use.	• Material: Porcine SIS • Material composition is identical to K034039 • Difference is the subject device is supplied pre-attached to a stainless steel trocar to facilitate placement • Nominal width of 1cm, nominal length of 15cm, and nominal thickness of 0.4mm (dry)
Permacol™	Tissue Science Lab-oratories, PLC	K992556	Permacol™ is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of **damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical, and incisional hernias; colon, rectal, urethral, and vaginal prolapse, muscle flap reinforcement; reconstruction of the pelvic floor and procedures such as sacrocolposuspension, and urethral sling.**	• Material: Porcine dermal collagen • Design: Variety of Shapes and Sizes based on Indication, thickness – 0.3 – 1.75mm
Permacol™ Crosslinked Porcine Dermal Collagen Surgical Mesh	Tissue Science Laboratories, PLC	K013625	Permacol™ issue is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for **plastic and reconstructive surgery of the face and head.**	• Material: Crosslinked porcine dermal collagen and its associated elastin fibers • Dimensions: Modified slightly from predicate, thickness 0.5 – 1.5mm, width 0.8 – 4.0mm length 1.2mm – 8mm

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Permacol™ Crosslinked Porcine Dermal Collagen Surgical Mesh	Tissue Science Laboratories, PLC	K021056	Permacol™- Crosslinked Porcine Dermal Collagen Surgical Mesh is indicated for use in the **reinforcement of the soft tissues which are repaired by suture or suture anchors limited to the supraspinatus during rotator cuff repair surgery.**	• Material: crosslinked porcine dermal collagen • Dimensions: 0.8" - 4" (W), 1.2" – 8" (L), and 0.5mm - 2.5mm (D)
Permacol® Surgical Implant Crosslinked Porcine Dermal Collagen Mesh	Tissue Science Laboratories, PLC	K043366	Permacol® is intended of use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the **repair of abdominal wall defects and hernias, including but not limited to parastomal hernias.**	• Device is identical to its predicate Permacol Surgical Implant (K992556) with only a few modifications made for the device used in rotator cuff surgery (K021056) • Dimensions: 1.3 in^2 to 96 in^2, Thickness - 1.0 & 1.5mm
Permacol® Surgical ImplantT-piece and Permacol® Surgical Implant Rectocele-piece	Tissue Science Laboratories, PLC	K050355	Permacol® Surgical Implants are intended for use to support / reinforce soft tissue in surgical procedures. Permacol Surgical Implant T-pieces are shaped for use in **rectal intussusception repair** and Permacol® Surgical Implant Rectocele-pieces are shaped for use in **rectocele repair**.	• The only difference between the predicate device and the subject devices is that the existing implants are rectangular and are intended to be cut to the desired shape by the physician
OptiMesh™	Spine-ology, Inc.	K014200	OptiMesh is intended to **maintain the relative position of bone graft material (such as autograft or allograft) within a vertebral body defect (e.g. tumor)** that does not impact the stability of the vertebral body and does not include the vertebral endplates.	• Porous, non-absorbable mesh graft containment device composed of polyethylene terephthalate (PET) thread. • Device has a drawstring closure to secure the OptiMesh neck after filling

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CuffPatch™	Organo-genesis, Inc.	K042809	CuffPatch™ surgical mesh is intended for reinforcement of soft tissues repaired by sutures or suture anchors, during tendon repair surgery including **reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons.** CuffPatch™ surgical mesh is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps or other tendon. Sutures, used to repair the tear, and sutures or bone anchors, used to attach the tissue to the bone, provide biomechanical strength for the tendon repair. CuffPatch™ surgical mesh reinforces soft tissue and provides a resorbable scaffold that is replaced by the patient's own soft tissue.	• Design - Laminated sheets of porcine intestinal collagen • Dimensions – 6.5 x 9 cm, 0.18-0.25mm in thickness • Identical in materials, design, physical characteristics, performance characteristics, and biological attributes to the FortaFlex (K011025)
Sportmesh	Arti-implant AB	K052830	Sportmesh™ is intended for use in general surgical procedures for **reinforcement of soft tissue where weakness exists.** Sportmesh™ is also intended for **reinforcement of soft tissues that are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery.** Sportmesh™ is not intended to replace normal body structure or provide the full mechanical **strength to support the rotator cuff. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to the bone, provide mechanical strength for the tendon repair.** Sportmeshr™ reinforces soft tissue and provides a degradable scaffold that is incorporated in the patient's own tissue.	• Knitted fabric made from ARTELON fibers (polycaprolactone based poly(urethane urea) material) • Dimensions: 4 x 6 cm, 0.6 – 0.9mm thick sheet

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Marlex Mesh	Davol	The sponsor references the following literature article on the Marlex Mesh: • Parrish F, Murray J, Urquhart B. 1978. The Use of Polyethylene Mesh (Marlex®) as an Adjunct in Reconstructive Surgery of the Extremities. *Clinical Orthopaedics and Related Research.* 1978; 137: 276-286. The sponsor tried to establish preamendment status of the Marlex Mesh (i.e. show the device was in interstate commerce prior to 1976) based on this literature article. As outlined in the Guidance Document on Preamendment Status (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm) sufficient documentation (requiring more than a literature reference) must be provided to our Office of Compliance to evaluate and determine the preamendment status of a device. Therefore, the Marlex Mesh is not considered a valid predicate device.		
Surgisis® ES Soft Tissue Graft	Surgisis	K062696	Surgisis® is intended for implantation to **reinforce soft tissue**. The device is intended for one-time use.	• Material: Porcine Small Intestine Submucosa • Dimensions: 0.6 cm x 5 cm to 20 cm x 30 cm • Thickness: 0.1 – 2.0mm
Surgisis® Gold™ Hernia Repair Graft	Surgisis	K062697	The SIS Hernia Repair Device is intended to be implanted to reinforce soft tissue where weakness exists. Indications for use include the **repair of a hernia or body wall defect**. The device is intended for one-time use.	• Material: Porcine Small Intestinal Submucosa • Sizes: 1 cm x 3 cm to 20 cm x 30 cm. • Multi-layered vacuum pressed sheets, available in perforated sheets. • Thickness: 100 pm to 1500 pm.

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IMMIX™ Thin Film	OsteoBiologics, Inc.	K024199	The IMMIX™ Thin Film is to be used wherever temporary wound support is required, to reinforce soft tissue where weakness exists, or for the repair of hernia or other fascial defects that require the addition of a reinforcing, or bridging material to obtain the desired surgical result. This includes, but is not limited to the following procedures: vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor and sacral colposuspension.	• Manufactured from poly(D,L-lactide-coglycolide) polymer • 10 x 10mm to 120 x 120mm sheets • Can be cut to other shapes and sizes • Thickness 50 – 300µm • Available with and without macroporous holes, hole diameters range from 100 – 1000 µm, holes may be aligned, offset, or random patterns